OCT 2 7 2006

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510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(K) submission guidance.

The assigned 510(K) number is: _____

1. **Submitter's Identifications:**

Mr. Mok Chi Wing
Choice Smart Health Care Company Limited.
RM 1901, CC WU BUILDING,
302 HENNESSY ROAD,
WANCHAI
Hong Kong
Phone (852) 28934110
Fax: (852)28934318

Date Summary Prepared: March 15, 2006

2. **Name of the device:**
   Rapid Digital Thermometer, Model RDT-18-XY (X=0-9, Y=1-9)
   Classification Name: Thermometer, Electronic, Clinical

3. **Predicate Device Information and Substantial Equivalence:**
   Electronic Thermometer GT010706 (K021052).

4. **Device Description:**
   The Rapid Digital Thermometer is an electronic thermometer by using a thermistor as the temperature sensor.

   The thermometer uses a 1.5V button battery for operation.

5. **Intended Use:**
   The Rapid Digital Thermometer is an electronic thermometer used to measure body temperature in oral, axillaries (underarm use), and rectal.

6. **Comparison to the 510(k) Cleared Device (Predicate Device):**

The Rapid Digital Thermometer (RDT-18 series) has the same intended use and technological characteristics as the cleared device of Electronic Thermometer GT010706 (K021052). Although there are slight differences between the new device and the legally marketed one, these differences do not affect the safety, performance of the subject device. So the new device is substantial equivalence to the selected predicate device.

7. **Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:**

Both the predicted device and the Rapid Digital Thermometer (RDT-18 series) are in compliance to applicable voluntary standards. Various performance testing data which conducted according to ASTM E1112 standards, such as temperature range test, accuracy test, resolution test, cleaning test, demonstrate the same safety and effectiveness as that of cleared device.

Also both devices conform to IEC 60601-1, IEC 60601-1-2 requirements, and as well as ISO 10993-1:2003 biocompatibility testing on skin irritation, in vitro cytotoxicity and sensitivity.

Guidance documents included the "FDA Guidance on the Content of Premark Notification (510(k)) Submission for Clinical Electronic Thermometers"

8. **Conclusions:**

The Rapid Digital Thermometer (RDT-18 series) has the same intended use and technological characteristics as the predicted device. Various performance testing data which conducted according to ASTM E1112 standards, such as temperature range test, accuracy test, resolution test, cleaning test, demonstrate the same safety and effectiveness as that of cleared device. In the other words, the Rapid Digital Thermometer is substantial equivalence to predicted device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Choice Smart Health Care Company Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
Laboratory and Testing
2600 NW Lake Road
Camas, Washington 98607-9526

OCT 27 2006

Re: K062016
Trade/Device Name: Rapid Digital Thermometer, Model RDT-18-XY(X=0-9, Y=1-9)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 10, 2006
Received: October 12, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

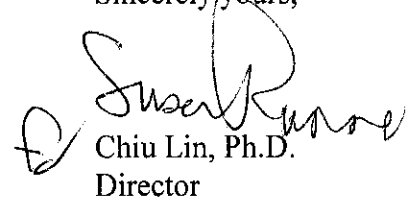
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062916

Indication for Use Statement

510(k) Number (if known):

Device name: Rapid Digital Thermometer, Model RDT-18-XY(X=0-9, Y=1-9)

Indications for Use:

It is an electronic thermometer used for clinical temperature measurement. It is intended for use at home and hospital environment for both children and adult.

Prescription Use _____ OR Over-The-Counter Use √
(Per 21CFR 801.109)

(PLESE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] of Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices

[illegible] K062916